

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  51D0694471	<b>(X3) Date Survey Completed</b>  08/24/2021
<b>Name of Provider or Supplier</b>  Cabin Creek Health Center	<b>Street Address, City, State</b>  5722 Cabin Creek Road, Dawes, WV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced, off site, proficiency testing (PT) desk review was conducted for Cabin Creek Health Center on August 24, 2021, by the West Virginia Office of Laboratory Services. The laboratory's PT evaluations with the American Academy of Family Physicians (AAFP) were reviewed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. The unsuccessful PT performance deficiencies are explained below.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on an off site desk review of the laboratory's 2021 American Academy of Family Physicians (AAFP) proficiency testing (PT) evaluation records and the</p>

	<p>CASPER 155D Individual Laboratory Profile Report, the laboratory failed to (c) successfully perform in a program approved by CMS for the analyte #0315 (Blood Gas pH) for 2 of 2 consecutive testing events in 2021. Findings: #0315 Blood Gas pH AAFP PT 2021-A 40% AAFP PT 2021-B 60%</p>
<p><b>D2096</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on an off site desk review of the laboratory's 2021 American Academy of Family Physicians (AAFP) proficiency testing (PT) evaluation records and the CASPER 155D Individual Laboratory Profile Report, the laboratory failed to attain a score of at least 80 percent of acceptable responses for analyte #0315 Blood Gas pH in 2 of 2 consecutive testing events for 2021. Findings: 1. Desk review of the CASPER 155D Individual Laboratory Report revealed the following unsatisfactory scores for analyte #0315 Blood Gas pH: 2021-A 40% 2021-B 60% 2. Review of AAFP PT evaluation records confirmed the unsatisfactory performance for analyte #0315 Blood Gas pH in 2 of 2 consecutive testing events of 2021.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the American Academy of Family Physicians (AAFP) proficiency testing (PT) evaluation reports and the CASPER 155D Individual Laboratory Profile report, the laboratory director failed to ensure successful participation in a program approved by CMS for the analyte #0315 Blood Gas pH for 2 of 2 consecutive testing events of 2021. Findings: 1. Refer to D2016 and D2096.</p>